NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 09-1426, 09-3598 and 09-4120

M.G.
by and through her parents and natural guardians,
K. and J.G.,

Appellant/Cross Appellee in 09-1426 and 09-3598

v.

A. I. DUPONT HOSPITAL FOR CHILDREN; NEMOURS FOUNDATION;
NEMOURS CARDIAC CENTER; WILLIAM I. NORWOOD,M.D.,PH.D; NUMED,INC.;
ALLEN J. TOWER; NEMOURS DE INSTITUTIONAL REVIEW BOARD;
JOHN MURPHY
Appellants/Cross Appellees in 09-4120

Appeals from the United States District Court
for the Eastern District of Pennsylvania
(D.C. Civil No. 2:08-cv-00228)
District Judge: Honorable R. Barclay Surrick

Argued July 12, 2010

Before: RENDELL, JORDAN and GREENAWAY, JR., Circuit Judges.

(Filed: August 24, 2010)

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OPINION OF THE COURT

RENDELL, Circuit Judge.

M.G. ("Plaintiff") appeals the District Court's grant of summary judgment on her claim of negligence in favor of defendants A.I. duPont Hospital for Children, the Nemours Foundation, the Nemours Cardiac Center, Nemours Delaware Institutional Review Board (collectively, the "Institutional Defendants"); Dr. William Norwood and Dr. John Murphy (the "Medical Defendants"); and NuMed, Inc. The Institutional Defendants, Medical Defendants, and NuMed (collectively, "Defendants"), cross appeal the District Court's denial of summary judgement on Plaintiff's medical monitoring claim. For the following reasons we will affirm the District Court's grant of summary

judgment as to the negligence claim and reverse the District Court's denial of summary judgment as to the medical monitoring claim.[1]

I.

Plaintiff was born with Down Syndrome and a combination of three heart defects that are uncommon but well-known congenital cardiac malformations that accompany Down Syndrome. As a result of her condition, Plaintiff underwent treatment at the A.I. duPont Hospital for Children in Wilmington, Delaware, where it was determined that a shunting procedure known as the Fontan procedure was the most appropriate treatment for Plaintiff's condition. The Fontan procedure modifies the physiology of the heart to deal with the primary effect of Plaintiff's heart defects—the inability of her heart to adequately pump blood to her lungs to be oxygenated. A Fontan physiology is typically created in a two-step process, a Hemi-Fontan followed by a surgical Fontan Completion, each of which traditionally requires open heart surgery. Here, the Medical Defendants achieved the Fontan Completion not through surgery, but through a relatively new catherization procedure ("Catherization Fontan") that included the implantation of a Cheatham Platinum Stent ("CP Stent"). The CP Stent had not been approved by the Food and Drug Administration, a fact unknown to Plaintiff's parents at the time of the procedure.

[1] Initially, the parents of three children, including Plaintiff, brought a class action. In April 2007, the parties stipulated to convert the action from a class action to separate civil actions. Only Plaintiff's case is before us.

Following implantation of the CP Stent and the creation of the Fontan physiology, Plaintiff began to develop protein losing enteropathy ("PLE") and plastic bronchitis ("PB"). PLE and PB are rare and life-threatening conditions, but are known complications of a Fontan physiology. Although initially under the care of the Medical and Institutional Defendants for treatment of her PLE and PB, Plaintiff's parents became dissatisfied with the care Plaintiff was receiving, and transferred her to the Children's Hospital of Pennsylvania ("CHOP"). While Plaintiff's PLE dissipated, her PB remained persistent, leading Plaintiff's physicians at CHOP to conclude that the best course of treatment would be to fenestrate, or put a hole in, the CP Stent. Eventually, Plaintiff's PB necessitated multiple fenestration procedures and the implantation of two additional stents. Plaintiff's physiological condition, underlying developmental issues, and continuing struggle with PB, necessitate ongoing medical care and surveillance.

Plaintiff's original complaint contained six distinct counts: (I) Negligence: Lack of Informed Consent, (II) Fraud and Intentional Misrepresentation, (III) Assault and Battery, (IV) Strict Products Liability, (V) Breach of Express and Implied Warranties, and (VI) Medical Monitoring. Plaintiff's complaint asserts that her "exposure to the NuMED CP Stent and Implantation Procedure . . . caused and will continue to cause [her] to suffer physical pain, mental anguish, medical and other related personal injuries and/or expenses." App. 149. Specifically, Plaintiff contended that "as a direct result of the stent placement and its resulting physiologic effects" she developed "at least two serious

medical conditions . . . Protein Losing Enteropathy (PLE) and plastic bronchitis [PB]." App. 158.

II.

On February 6, 2009, the District Court issued two memoranda and accompanying orders, one resolving the claims against the Medical and Institutional Defendants (hereinafter, "First Memorandum"), the other resolving the claims against NuMED, Inc. and its CEO Allen Tower (hereinafter, "Second Memorandum").

A. First Memorandum

In the First Memorandum, the District Court applied Delaware law[2] and noted that the Delaware Health Care Malpractice Insurance and Litigation Act (the "Health Care Act"), 18 Del. C. §§ 6801 *et seq*., governed the claims at issue, since it defines medical negligence in an all-encompassing manner as "any tort or breach of contract based on health care or professional services rendered, or which should have been rendered, by a health care provider to a patient." App. 23 (citing 18 Del. C. § 6801(7)). The District Court continued:

> A cornerstone of the Health Care Act is the requirement that plaintiffs asserting claims against healthcare providers must

[2] The District Court conducted a choice of law analysis that is uncontested on appeal. The District Court found Delaware law applicable because, although Plaintiff is from New Jersey and Pennsylvania is the forum state, the complained-of conduct occurred in Delaware, Plaintiff intentionally traveled to Delaware to receive treatment, and Delaware has an interest in regulating activity within its borders and maintaining the predictability of its health care regulations.

> support those claims with expert testimony regarding the healthcare provider's deviation from the standard of care and the causal connection between the healthcare provider's deviation and plaintiff's injury. *See* 18 Del. C. § 6853(e) ("No liability shall be based upon asserted negligence unless expert medical testimony is presented as to the alleged deviation from the applicable standard of care in the specific circumstances of the case and as to the causation of the alleged personal injury or death . . . ."). Indeed, the testimony of a competent medical expert is an essential element of any medical negligence claim, including informed consent claims, in Delaware.

App. 24. The District Court found that Plaintiff's medical negligence, lack of informed consent, and fraud claims all failed because Plaintiff did not satisfy her burden of producing medical expert testimony that established causation.[3] Accordingly, the District Court granted the motions for summary judgment with respect to these claims.

The District Court allowed Plaintiff's "Medical Monitoring" claim to proceed, denying the motion for summary judgment with respect to this count. The District Court acknowledged that, although Pennsylvania and New Jersey recognize medical monitoring as a cause of action, in Delaware, "it is not clear whether medical monitoring is an independent tort or whether medical monitoring is simply a remedy, as it is in many other jurisdictions." App. 22. The District Court noted that the "Delaware Supreme Court has

[3] The District Court had previously dismissed Plaintiff's assault and battery claim, strict liability claim, and breach of express and implied warranties claim against Dr. Norwood and Dr. Murphy, and extended that conclusion to the Institutional Defendants in this decision. Plaintiff does not address this issue or these claims in her opening brief, and so these claims have been waived.

acknowledged medical monitoring but has never explicitly recognized medical monitoring as a legally cognizable cause of action," and that, as a result, the District Court sitting in diversity "must predict how the state's supreme court would resolve the issue, giving consideration to the decisions of intermediate state courts." App. 39. The District Court then predicted that the Delaware Supreme Court would permit a claim for medical monitoring on this record. The District Court suggested that because Defendants caused Plaintiff to come into contact with an adulterated medical device and this contact (and the continued presence of the device in Plaintiff's body) will require Plaintiff to receive continued medical monitoring specifically with respect to the effects of the CP Stent, Plaintiff might be able to sustain a medical monitoring claim.

B. Second Memorandum

In the Second Memorandum, which dealt with the claims against NuMED, Inc. (the manufacturer of the CP Stent), and Allen Tower (the sole shareholder and CEO of NuMED, Inc.), the District Court again found that Delaware law applied with respect to the various tort claims in Counts I through V, and that, again, Plaintiff's claims were blocked due to her inability to demonstrate causation.[4] Plaintiff does not argue for reversal of summary judgment on any of these five counts with respect to either NuMED or Tower, including the lack of informed consent claim, and so these issues have been

[4] The District Court dismissed Plaintiff's strict liability claim on the grounds that Delaware law bars strict product liability claims, and the breach of express and implied warranties claims failed for a variety of non-causation related reasons.

waived.

The District Court denied NuMED's motion for summary judgment as to Count VI (the medical monitoring claim) with respect to NuMED, for the same reasons that it denied the motion for summary judgment in the other decision. The District Court granted the motion for summary judgment with respect to Allen Tower, on the grounds that, applying New York law (through a new choice of law analysis), Plaintiff failed to prove "complete domination" and to pierce the corporate veil. Again, Plaintiff does not argue for reversal of the entry of judgment in favor of Allen Tower in her opening brief, and so that issue is waived.

C. Remaining Issues on Appeal

Although Plaintiff's Notice of Appeal indicated that she was appealing the dismissal of Counts I through V, the only one of these five counts she addressed in her Opening Brief is her negligence-based lack of informed consent claim set forth in Count I of her Complaint against the Medical Defendants and the Institutional Defendants. Accordingly, the other issues have been waived. *See Tracinda Corp. v. DaimlerChrysler AG*, 502 F.3d 212, 236 n.18 (3d Cir. 2007) ("[I]t is well-settled in this court that an appellant's failure to identify or argue an issue in his opening brief constitutes waiver of that issue on appeal." (internal quotation marks and citations omitted)); *United States v. Pelullo*, 399 F.3d 197, 201 n.2 (3d Cir. 2005) ("Where, as here, an appellant fails to raise an issue in an appellate brief, even if it was listed in the Notice of Appeal, it is deemed

waived."), *cert denied*, 546 U.S. 1137 (2006).

NuMED, the Medical Defendants, and the Institutional Defendants all cross appeal the denial of summary judgment on the medical monitoring claim.

III.

The District Court had jurisdiction pursuant to 28 U.S.C. § 1332. We have jurisdiction over Plaintiff's appeal pursuant to 28 U.S.C. § 1291, and over the Defendants' cross-appeal pursuant to 28 U.S.C. § 1292(b). We exercise plenary review over a grant or denial of summary judgement and apply the same standard used by the District Court. *Giles v. Kearney*, 571 F.3d 318, 322 (3d Cir. 2009). A grant of summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). We view the facts in the light most favorable to the nonmoving party, drawing all reasonable inferences in the non-movant's favor. However, "[t]he mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonablely find for the plaintiff." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 252 (1986).

A. Negligence: Lack of Informed Consent

As the District Court noted, medical negligence actions brought under Delaware law are governed by the Health Care Act. The Health Care Act defines medical

negligence as "any tort or breach of contract based on health care or professional services rendered, or which should have been rendered, by a health care provider to a patient." 18 Del. C. § 6801(7). Under section 6853, titled "Affidavit of Merit, expert medical testimony," the Health Care Act explicitly states:

> No liability shall be based upon asserted negligence unless expert medical testimony is presented as to the alleged deviation from the applicable standard of care in the specific circumstances of the case and as to the causation of the alleged personal injury or death . . .

18 Del. C. § 6853(e). Thus, under the Health Care Act, a claimant must show, by expert medical testimony, (1) the applicable standard of care, (2) the deviation from that standard, and (3) that this deviation caused the alleged personal injury or death. Delaware law requires that causation meet the "but for" causation standard, *see Edwards v. Family Practice Associates, Inc.*, 798 A.2d 1059, 1066 (Del. Super. Ct. 2002) ("Plaintiffs must show such negligence was a proximate cause of injury; that is, but for the negligence, the injury would not have happened."), which means that the claimant must show that the harm would not have occurred if not for the defendant's deviation from the standard of care. *See Burkhart v. Davies*, 602 A.2d 56, 59 (Del. 1991).

The Informed Consent Statute of the Health Care Act, 18 Del. C. § 6852, is contained within, and governed by, the "Medical Negligence" chapter of the Delaware Code. *See Brzoska v. Olson*, 668 A.2d 1355, 1366 (Del. 1995) ("If a health care provider violates his or her duty of care in obtaining the consent of the patient by failing to disclose

all relevant information (risks) that a reasonable person would deem significant in making a decision to have the procedure, the action should be pleaded in negligence—not battery."). The Health Care Act defines informed consent as:

> the consent of a patient to the performance of health care services by a health care provider given after the health care provider has informed the patient, to an extent reasonably comprehensible to general lay understanding, of the nature of the proposed procedure or treatment and of the risks and alternatives to treatment or diagnosis which a reasonable patient would consider material to the decision whether or not to undergo the treatment or diagnosis.

18 Del. C. § 6801(6). Consequently, as with other claims under the Health Care Act, to succeed on a lack of informed consent claim such as this one, a plaintiff must show that by failing to obtain informed consent, a defendant fell below the applicable standard of care. In particular, the claimant must prove "by a preponderance of evidence that the health care provider did not supply information regarding such treatment, procedure or surgery to the extent customarily given to patients, or other persons authorized to give consent for patients by other licensed health care providers in the same or similar field of medicine as the defendant." 18 Del. C. § 6852(a). The plaintiff must also show that the deviation from the standard of care caused the harm, supporting this evidentiary burden with the presentation of expert testimony. This requirement has been explicitly applied to lack of informed consent claims. *See Valentine v. Mark*, 2004 WL 2419131, at *3 (Del. Super. Ct. Oct. 20, 2004) ("More importantly, an informed consent action still requires expert testimony as to causation. . . . Section 6853 makes it abundantly clear that . . . only

expert testimony can prove the essential element of causation. Section 6852 [the informed consent provision] cannot therefore be used as a backdoor around the requirement that causation in medical negligence cases be supported by expert testimony."). Accordingly, in order to prevail on a cause of action for informed consent, Delaware law requires a claimant to show not just a deviation from the standard of care, but to show by expert testimony that the deviation complained of is the "but for" cause of a legally cognizable harm.

We agree with the District Court that Plaintiff has not presented the necessary expert testimony to demonstrate that the deviation from the standard of care by the Defendants was the "but for" cause of the harm she suffered. Plaintiff has demonstrated that following the Catherization Fontan and the implantation of the CP Stent, she suffered from PLE and continues to struggle with PB. However, the complications suffered by Plaintiff are known complications of the Fontan physiology, and Plaintiff did not produce expert medical testimony showing that these harms were caused by the Defendants' failure to inform as to the use of the CP Stent or by the Catherization Fontan. The only medical expert Plaintiff produced, Dr. Paul Grossfeld, testified that PLE and PB are both known complications of the Fontan physiology that can and do develop even in the absence of negligence by the treating physician. App. 242-44. In response to the direct question of whether Plaintiff's complications were due to the CP stent or the use of the catherization procedure, Dr. Grossfeld replied "I don't know," and "I don't know. I think

that's unlikely," respectively. App. 243-44.

The District Court's conclusion seems inescapable. Plaintiff did not meet her burden with respect to causation, and summary judgment was appropriately granted with respect to this claim.[5]

B. Medical Monitoring

Plaintiff's original sixth cause of action was a claim entitled "Medical Monitoring." She contended that "[a]s a direct result of defendants' acts, omissions, and conduct, plaintiffs . . . who have received NuMED CP stent have been exposed to a

[5] Plaintiff urges on appeal that her harm is not limited to PLE and PB, but also includes the harm of being required "to undergo multiple procedures to fenestrate [the CP Stent]," Appellant's Br. 48, and to undergo "additional procedures to expand the stent as she grows" in the future. Appellant's Resp. Br. 11. Plaintiff contends that her parents would not have consented to the CP Stent implantation if they had been given all of the information. Accordingly, Plaintiff urges that the multiple fenestration procedures she had to undergo at CHOP, as a result of the CP Stent, and the created need to dilate or expand the stent in the future, represent harm that but for Defendants' actions (in proceeding without informed consent) she would not have to endure.

In response, Defendants urge that the treatment Plaintiff underwent at CHOP—the fenestration procedures—are a result of known complications of Fontan physiology that Plaintiff would have had to undergo regardless of whether the Fontan was completed by surgery or catheter. Defendants' position is that if surgical completion had taken place, Plaintiff would have had a Gore-Tex tube implanted, which would have required Plaintiff's CHOP doctors to punch a hole or fenestrate the same Gore-Tex material that was used for the CP Stent.

We note, first, that Plaintiff did not specifically identify the need to undergo multiple fenestration procedures as a harm in her initial complaint. Even leaving this concern aside, Plaintiff's argument is unavailing as she does not identify any expert testimony in the record that establishes that Defendants' actions were a "but for" cause of the need for multiple fenestration procedures.

hazardous procedure and product, and suffered a significantly increased risk of the side effects caused by this device. This increased risk makes periodic diagnostic and medical examinations reasonable and necessary." App. 178. The complaint continued:

> "Medical monitoring is necessary because: (a) The NuMED CP Stent is a proven and admittedly hazardous product; (b) Plaintiffs' exposure to the hazardous product and procedure was proximately caused by defendants' tortious conduct; (c) Medical monitoring will detect injuries from the NuMED CP Stent and its implantation; (d) This monitoring will be different from what normally is recommended to individuals who did not receive a NuMED CP Stent; and (e) Medical monitoring will assist in preventing further injuries from or as a consequence of implantation of the NuMED CP Stent."

App. 178-79. Plaintiff posed the medical monitoring claim as an independent cause of action, not merely as a remedy for negligence or some other tortious conduct, despite condition (b), which refers to "defendants' tortious conduct."

As noted above, the District Court allowed Plaintiff's "Medical Monitoring" claim to proceed, denying the motion for summary judgment with respect to that count. The District Court acknowledged that in Delaware, "it is not clear whether medical monitoring is an independent tort or whether medical monitoring is simply a remedy, as it is in many other jurisdictions." App. 22. The District Court noted that the "Delaware Supreme Court has acknowledged medical monitoring but has never explicitly recognized medical monitoring as a legally cognizable cause of action," and that, as a result, the District Court sitting in diversity "must predict how the state's supreme court would resolve the issue, giving consideration to the decisions of intermediate state courts." App.

39. The District Court then predicted that the Delaware Supreme Court would permit a claim for medical monitoring on this record.

In an August 28, 2009 Order, the District Court certified the following three issues for immediate interlocutory appeal to this Court:

> 1) Would the Delaware Supreme Court recognize a medical monitoring cause of action if presented with the record in this case?
>
> 2) If the appellate court answers the first certified question in the affirmative, would Plaintiff be able to state a claim for medical monitoring in Delaware?
>
> 3) If the appellate court answers the first two certified questions in the affirmative, would Plaintiff meet her summary judgment burden of establishing a genuine issue of fact for trial regarding her medical monitoring claim?

App. 99-100.

Because we find that Plaintiff is unable to establish the elements necessary to state a claim for medical monitoring, we decline to reach the questions posed by the District Court, and will, for the following reasons, reverse the denial of summary judgement.

Defendants argue that the District Court erred in predicting that the Delaware Supreme Court would adopt a stand-alone cause of action for medical monitoring. In particular, Defendants contend that the District Court erred in extending Delaware law beyond the bounds of the recognized medical monitoring claim in which a plaintiff alleges long-term exposure to a proven toxic substance with known tendencies to produce serious future medical injuries. We agree.

Neither the District Court nor Plaintiff points to any case in this Circuit, let alone

in Delaware, in which a free-standing medical monitoring claim has been allowed to proceed although the plaintiff has not demonstrated significant exposure to a toxic (poisonous) or proven hazardous substance.[6] Medical monitoring was addressed by this Court in litigation surrounding the plaintiffs' exposure of polychlorinated biphenyls (PCBs) from working in or living adjacent to a rail-yard. *In re Paoli Railroad Yard PCB Litigation*, 916 F.2d 829 (3d Cir. 1990) (*Paoli I)*; 35 F.3d 717 (3d Cir. 1994) (*Paoli II)*; 113 F.3d 444 (3d Cir. 1997) (*Paoli III*). In *Paoli II*, this Court found that medical monitoring is a viable claim under Pennsylvania law and re-articulated the following test from *Paoli I*, concluding that these elements are necessary to make out a medical monitoring claim in Pennsylvania:

> 1. Plaintiff was significantly exposed to a proven hazardous substance through the negligent actions of the defendant.
>
> 2. As a proximate result of exposure, plaintiff suffers a significantly increased risk of contracting a serious latent disease.
>
> 3. That increased risk makes periodic diagnostic medical examinations reasonably necessary.

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[6] The Delaware Supreme Court has not recognized a cause of action for medical monitoring, a fact the District Court acknowledged. The District Court notes that courts in Delaware have "acknowledged" medical monitoring tacitly without "expressly addressing its viability as a cause of action." App. 39 n.8 (citing *Alderman v. Clean Earth, Inc.*, No. 04C-06-181, 2007 Del. Super. LEXIS 191, at *8 (Del. Super. Ct. June 26, 2007); *Brzoska v. Olsen*, No. 92C-06-142, 1994 Del. Super. LEXIS 230, at *9 (Del. Super. Ct. May 2, 1994), *aff'd in part, rev'd on other grounds*, 668 A.2d 1355 (Del. 1995); *In re Asbestos Litig.*, No. 87C-09-24, 11994 Del. Super. LEXIS 685, at *5 (Del. Super. Ct. Aug. 5, 1994)).

> 4. Monitoring and testing procedures exist which make the early detection and treatment of the disease possible and beneficial.

35 F.3d at 787. Plaintiff identifies a single case, *Sutton v. St. Jude Med, S.C., Inc.*, 419 F.3d 568 (6th Cir. 2005), in which a court suggested that recovery of future medical costs might be appropriate outside of the "toxic tort" context. In *Sutton*, the Sixth Circuit found that Sutton had standing to seek medical testing and monitoring allegedly made necessary by the implantation of a medical device that had not yet malfunctioned or caused Sutton any physical injuries. *Id*. at 575. The *Sutton* Court only discussed basic standing doctrine; it did not find that Sutton could recover for medical monitoring, nor did it find that medical monitoring could be applied as a free-standing tort claim in a non-toxic tort scenario.

Thus, the District Court's prediction that the Delaware Supreme Court would permit a claim for medical monitoring on this record requires several "leaps" from the current state of the law, generally, let alone Delaware law. Here, there is no toxic or hazardous substance, as such. While unapproved devices are termed "adulterated", they are not necessarily harmful, and certainly not toxic. Moreover, the risk here is not a risk of "contracting a serious latent disease." Rather, it is a risk of the need for further care. Further examinations are not to "monitor" the risk of disease, but to perform routine oversight.

In reaching this conclusion, we decline to predict whether the Delaware Supreme

Court might acknowledge some variant of a medical monitoring claim. Even if the Delaware Supreme Court would recognize a "standard" medical monitoring claim, such as the one identified in *Paoli*, which requires a plaintiff to demonstrate that a defendant's negligence caused the plaintiff to be exposed to a proven hazardous substance that resulted in a significantly increased risk of contracting a serious latent disease, the plaintiff here cannot demonstrate that she has been exposed to a proven hazardous substance, nor can she prove that such exposure resulted in a significantly increased risk of contracting a serious latent disease.[7] Accordingly, we find that Plaintiff is unable to establish the elements necessary to make out a claim for medical monitoring. For the foregoing reasons, we reverse the order of the District Court denying Defendants' motions for summary judgment.

IV.

The District Court is hereby affirmed in part and reversed in part.

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[7] We also note the well-established principle that a federal court sitting in diversity, when called upon to make a prediction of state law, should act conservatively. *See, e.g.*, *Day & Zimmerman, Inc. v. Challoner*, 423 U.S. 3, 4 (1975) (per curiam) ("A federal court in a diversity case is not free to engraft onto those state rules exceptions or modifications which may commend themselves to the federal court, but which have not commended themselves to the State in which the federal court sits."); *Travelers Indemnity Co. v. Dammann & Co, Inc.*, 594 F.3d 238, 253 (3rd Cir. 2010) ("[I]n reaching our conclusion we have exercised restraint in accordance with the well-established principle that where 'two competing yet sensible interpretations' of state law exist, 'we should opt for the interpretation that restricts liability, rather than expands it, until the Supreme Court of [that state] decides differently'." (internal citations omitted)).